

FEB 07 2005

IN THE UNITED STATES DISTRICT COURT
 FOR THE NORTHERN DISTRICT OF MISSISSIPPI
 GREENVILLE DIVISION

BY *Arlene B. Coyle, Clerk*
J. St. John
 Deputy

HEATH WILLIAM KNIGHT, ET AL

PLAINTIFFS

v.

CAUSE NO. 4:01CV223 - P - B

KIRBY INLAND MARINE, INC.; ET. AL.

DEFENDANTS

**DEFENDANTS' KIRBY INLAND MARINE, INC., ET. AL.
POST-HEARING MEMORANDUM IN SUPPORT OF THEIR MOTION IN LIMINE**

MAY IT PLEASE THE COURT:

Standard of Admissibility for Expert Testimony

From a procedural standpoint, *Daubert v. Merrill Dow Pharmaceuticals, Inc.* 509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed 2d 469 (1993), instructs us that the District Court must determine admissibility under Rule 702, F. R. E., by following the directions provided in Rule 104(a), F. R. E., which require the District Judge to conduct preliminary fact finding, and, afterwards, to make a "preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." *Moore v. Ashland Chemical Co., Inc.* 151 F.3d 269 (5th Cir. 1998), citing *Daubert, supra.*, 509 U.S. at 592-93, 113 S. Ct. at 2796.

The admissibility of all expert testimony is governed by the principles of Rule 104(a), F. R. E. Under that rule, the proponent (the Plaintiffs in this case) has the burden of establishing that the pertinent admissibility requirements are met by a preponderance of the evidence. *Id.* at 276. See also *Allen v. Pennsylvania Engineering Corp.*, 102 F. 3d 194, 198 (5th Cir. 1996); *Daubert, Supra*, 509 U.S. 592, n. 10 (citing 104(a) F.R.E.).

Daubert interprets Rule 702, F. R. E., by explaining that the Rules of Evidence give to the District Court Judge a "gatekeeping" role to insure that scientific testimony is both reliable and relevant. *Curtis v. M & S Petroleum, Inc.*, 174 F. 3d 661 (5th Cir. 1999), citing *Daubert, supra.*,

509 U. S. at 597, 113 S. Ct. at 2799. *Amoginos v. National Railroad Passenger Corporation*, 303 F. 3d 256, 265 (2nd Cir. 2002).

In order for the challenged testimony to be reliable, the subject of the testimony must be “scientific knowledge” that will assist the trier of fact to understand or determine a fact in issue. *Daubert, supra.*, 509 U. S. at 592. This requirement implies that the testimony must be grounded in the methods and procedures of science and must be more than unsupported speculation or subjective belief. *Curtis, supra.*, citing *Moore, supra.*, at 276.

The Court must examine an expert’s methodology and conclusions in order to assure reliability. *Daubert*, Supra 509 U.S. at 592; *General Electric Co. v. Joyner*, 522 U. S. 136, 146, 118 S. Ct. 512, 519 (1997). The *Joyner* Court stated:

Conclusions and methodology are not entirely distinct from one another. Trained experts commonly extrapolate from existing data. But nothing in either *Daubert* or the Federal Rules of Evidence require a District Court to admit opinion evidence which is connected to existing data only by the *ipse dixit* (“it is because I say”) of the expert. The Court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.

The Supreme Court recognized in *Joyner*, that both methodology and conclusion are subject to the same rigorous subjective review.

The Supreme Court, in *Daubert*, set forth four main questions or criteria to be answered in determining whether a theory or technique is scientific knowledge that will assist the trier of fact. The first criteria is whether it can (or has been) tested. “Scientific methodology today is based on generating hypotheses and testing them to see if they can be falsified; indeed, this methodology is what distinguishes science from other fields of human inquiry.” *Daubert, supra.*, 509 U. S. at 593 (citations omitted).

The second pertinent consideration set forth in *Daubert* is whether the theory or technique has been subject to peer review and publication. *Id.* While publication is not a *sine qua non* of admissibility, submission to the scrutiny of the scientific community is a component of “good

science,” in part because it increases the likelihood that substantive flaws in methodology will be detected. *Id.* (citations omitted).

The third criteria the Court should consider is the known or potential rate of error. *Id.*

The last *Daubert* criteria is whether or not the methodology or conclusions have been generally accepted within the scientific community. *Id.* (citations omitted). While wide-spread acceptance can be an important factor in finding that particular evidence is admissible, “a known technique which has been able to attract only a minimum of support within the community,” may properly be viewed with skepticism. *Id.*, citing *United States v. Downing*, 753 F. 2d, 1224, 1238 (3d. Cir. 1985).

Both before and after *Daubert*, courts have found other factors relevant in determining whether expert testimony is efficiently reliable to be considered by the trier of fact. Advisory Committee notes 2000 Amendments Rule 702 F.R.E. See attached as Exh. 1. These factors include:

1. Whether experts are “proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinion expressly for purposes of testifying.” (Citing *Daubert*).
2. Whether the expert has unjustifiably extrapolated from an accepted premise to an unfounded conclusion. (Citing *General Electric Co. v. Joyner*...).
3. Whether the expert is adequately accounted for all obvious alternative explanations. (Citing *Claar v. Burlington N.R.R.*, 29 F. 3d 499 (9th Cir. 1994)...).
4. Whether the expert “is being as careful as he would be in his regular professional work outside his paid litigation consulting.” *Sheehan v. Daily Racing Form, Inc.*, 104 F. 3d 940-942 (7th Cir. 1997). See *Kumho Tire*...at 1176.
5. Whether the field of expertise claimed by the expert is known to reach reliable results for the type of opinion the expert will give. See *Kumho Tire*... at 1175.

All of these factors remain relevant to the determination of the reliability of expert testimony under the rule as amended.

In toxic court cases, courts have not allowed expert testimony when that testimony is not grounded in methods and procedures of science. The courts have held that any step of an expert's methodology that renders the analysis unreliable, renders the expert's opinion inadmissible. *Paoli Railroad Guard PCB Litigation*, 35 F. 3d 717, 745 (3rd Cir. 1994); *Curtis v. M & S Petroleum, Inc.*, 174 F. 3d 661, 670-71 (5th Cir. 1999).

Also, the Fifth Circuit has held that “[s]cientific knowledge of the harmful level of exposure to a chemical, plus knowledge that the plaintiff was exposed to such quantities, are minimum facts necessary to sustain the plaintiff's burden in a toxic tort case.” *Allen v. Pennsylvania Engineering Corp.*, 102 F. 3d 194, 199 (5th Cir. 1966). See also *Wright Willamette Industries, Inc.*, 91 F. 3d 1105, 1106 (8th Cir. 1996).

Methodology of Plaintiffs' Expert

Dr. Levy's methodology consisted of 1) identifying the pertinent and relevant articles in the medical and scientific literature; 2) look at the soundness of the individual articles; and 3) examine the body of literature and apply the Bradford-Hill principles. Nov. TR 6.

In essence, Dr. Levy's methodology entails a “weight of the evidence” evaluation. “When a weight-of-the-evidence evaluation is conducted, all of the relevant evidence must be gathered, and the assessment or weighing of that evidence must not be arbitrary, but must itself be based on methods of science.” *Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 602 (Dist. Ct. NJ, 2002). In addition, the application of that methodology must also be reliable and grounded in the methods of science. Id.

In the instant case, Dr. Levy either failed to identify or refused to identify the two large cohort studies (Pliofilm and Chinese) that are accepted by the Environmental Protection Agency (EPA), the Agency for Toxic Substances and Disease Register (ATSDR), and International Agency

for Research on Cancer (IARC), and the National Cancer Institute (N.C.I.) as the most relevant and pertinent studies on the carcinogenicity of benzene. In fact, Dr. Levy did not cite or rely on the most up to date assessments of the carcinogenicity of benzene produced by the governmental agencies that are charged with the responsibility of our nation's health. Unbelievably, Dr. Levy stated that he was not even aware of the 1998 EPA update (Def. Exh. 8) when he prepared his affidavit in August, 2004. Dec. TR 46. He stated that the first time he saw the update was when I showed it to him on Nov. 29th, the first day of the hearing. Nov. TR 46. On cross examination, he admitted he had seen the 1998 update in August, 2004, during a deposition in another case. Dec. TR 80. Both Dr. Gori and Dr. Borgert testified that the most relevant and pertinent literature on the carcinogenicity of benzene are the studies that came out of the Pliofilm and Chinese cohorts. Both agreed that the 1998 EPA update, ATSDR Toxicological Profile on benzene (Defs' Exh. 15), and IARC benzene monograph (Defs' Exh. 11) are the most up to date and thorough pronouncements on the carcinogenicity benzene. Gori TR 233-236. Borgert TR 369-370; 383-384. The Fifth Circuit has recognized that the Toxicological Profile (Defs' Exh. 15) as containing all the knowledge as far as epidemiology and animal studies about its toxicity of benzene and its adverse health effects. See *Curtis*, supra at pp. 669-70. The is no question that the ATSDR Toxicological Profile is the most expansive pronouncement on the effects of benzene. Of major importance is the fact that all these governmental documents are rigidly peer reviewed. See forward on each.

Dr. Gori further stated that all the governmental agencies have determined that the Pliofilm and Chinese cohorts are the most credible epidemiology studies in terms of results because largely, they were able to reconstruct exposure and dosage. Dec. TR 241. Additionally, they were able to isolate one chemical "benzene" and none of the studies relied upon by Dr. Levy were able to isolate any chemical. Dec. TR 242.

The Pliofilm studies followed thousands of workers for over fifty years and found no increased risk from exposure to benzene for any solid tumors. Both bladder cancer and Hodgkin's disease are solid tumors. Dec. TR 244; 396-399.

Levy took the position that he did not consider the Pliofilm or Chinese cohorts because they looked primarily at leukemia. Nov. TR 120, 135. All Defendants' experts stated the Pliofilm and Chinese cohorts looked at all cancers. Dec. TR 243, 321, 385. Later he admitted that the Chinese cohort looked at all diseases, and if there was a significant increase in any disease, it would have been reported. Dec. TR 99.

Dr. Borgert stated it was absolutely inconceivable to him that an expert epidemiologist could search the medical literature and fail to find the Pliofilm cohorts, failed to understand that the EPA and IARC have based their evaluations of the carcinogenicity of benzene looking at all cancers on the body of literature (Pliofilm and Chinese cohorts) that Dr. Levy failed to even consider. Dec. TR 370.

The ATSDR Toxicological Profile for benzene, the 1998 EPA update, and the EPA Integrated Risk Information System (IRIS) 2003 update only recognize a causal association between exposure to benzene and certain forms of leukemia. Dec. TR 235, 237, 240. Dr. Gori also was very critical of Dr. Levy's methodology of selecting the studies he relied upon because he failed to consider the best studies, and best literature on the subject matter calling Dr. Levy's selection process transparent and subjective. Dec. TR 261-262.

Dr. Levy also failed to identify or consider the Bloeman study (Defs' Exh. 7) which he admitted was the most up to date study published in 2004 on benzene cancer risk. Dec. TR 60-62. While he stated that he did not know if he was aware of the Bloeman study before writing his affidavit, he did admit reviewing it this past fall in relation to another matter. Dec. TR 51. Although

he agreed that the Bloeman study was relevant to the issues in this lawsuit, he did not use that in his analysis. Dec. TR 60.

After testifying he was not aware of any other studies that addressed benzene exposure, bladder cancer and Hodgkin's disease, he was reminded by Defendants' counsel that he prepared a report in the *Watts* case, working at the same time on the affidavit he prepared in our case. In the *Watts* case, his opinion was that benzene caused non-Hodgkin's lymphoma and he relied upon several studies that he failed to identify in our case which specifically dealt with benzene and Hodgkin's disease and bladder cancer. Dec. TR 83 through 98. The Wong study, Defs' Exh. 18, study #4, specifically isolated benzene and found no increased risk for bladder cancer or Hodgkin's disease. The Hayes study, Defs' Exh. 18, study #10, no Hodgkin's disease was reported. The Pukkala study, Exh. 18, study #15, would a little, if any risk, for bladder cancer and Hodgkin's disease. The Raabe study, Defs' Exh. 18, #16, revealed no risk association with benzene and Hodgkin's disease or bladder cancer. He admitted that these studies were relevant to the issues, but he overlooked them. Dec. TR 98.

It is incredible to believe that an expert of his alleged credentials could either overlook pertinent and relevant studies or not be aware of these studies.

Levy admitted that if his first step (identifying all pertinent publications) was faulty or defective, then as a general statement, the next two steps would be defective. Nov. TR 93-94.

It is evident that Dr. Levy did not consider all of the relevant and pertinent literature; and because of this, his methodology certainly does not rise up to what is required using the scientific method; and at best, was a feeble attempt to selectively review only materials that allegedly on the surface found some type of positive association with benzene and the respective cancers.

Because of this and this alone, his opinions are inadmissible.

Even if you look at the studies that he did identify and use to form his opinions, the second step of his methodology, looking at the soundness of the studies, also falls short an admissibility.

There is no question that Dr. Levy not only “cherry-picked” the literature to review, but then “cherry-picked” the data within the literature to come up in almost every instance with a higher risk association using data which did not apply to the respective Plaintiffs. He completely ignored statements from the author and data which contradicted his conclusion.

Cross examination of Dr. Levy concerning all studies reveal that in almost every study, there were discrepancies in what the authors said; and the appropriate data that should have been utilized instead of the data which only showed the highest increased risk. See the attached table as Exh. 2 as examples of the “cherry-picking” of data.

It is evident from reviewing the cross-examination of Dr. Levy that he selectively picked, out of each study, the data which would most support his opinion and failed to consider in many cases, data that was more closely related and applicable to the Plaintiffs. Both Dr. Gori and Dr. George Casella, severely criticized Dr. Levy’s “cherry-picking” of data within the studies. Dec. TR 263-266; 315, 317-318, 322, 333-334, 345.

Application of the Bradford-Hill Standards

Strength. There is no question that this standard was not met when you look at all the relevant literature and the appropriate data contained in that literature. Dr. Levy claims the relative risk of 2 or higher on both the Hodgkin’s disease cases and the bladder cases; however, if you look solely at his studies that he relied upon, considered the data most closely associated with each Plaintiff, the relative risk as determined by Dr. Casella’s meta analysis on the bladder cancer showed a relative risk of .894 for diesel and all sources and 1.198, and Hodgkin’s disease of 1.348. See Meta Analysis, Exhibit 21. Dec. TR 330. However, if you considered the studies relied upon by

Defendants, along with Levy's studies, the relative risk would move closer to 1 or no risk at all. Dec. TR 331.

Consistency. There is no question there is no consistency between even Dr. Levy's studies, but certainly not between the studies relied upon by Dr. Levy and the studies relied upon by Dr. Borgert and Dr. Gori, and the governmental agencies. Dec. TR 257-258.

Biological Plausibility. Both Dr. Gori and Dr. Borgert testified that based upon the scientific knowledge that we have today, it is not biologically plausible for benzene to cause either Hodgkin's disease or bladder cancer. Dr. Levy found biological plausibility, but stated that he did not consider mechanism in his analysis. Dr. Borgert testified that there is no way you can consider biological plausibility without an analysis of mechanism of the disease. When you look at the mechanism of both diseases, it is evident that the standard of biological plausibility is not meet. Dec. TR 252-253, 260, 388, 390.

Specificity. This principle certainly was not meet because it suggest that a causal factor only causes one disease, and in the instant case, Dr. Levy has taken the position that exposure to benzene causes Hodgkin's to diseases.

Biological Gradient/Dose Response. Even Dr. Levy admitted that this standard was not meet because in many of the studies utilized by Dr. Levy, when the dosage increase, the instances of disease decreased. Nov. TR 197. Dec. TR 259.

Coherence. Both Dr. Gori and Dr. Borgert state that this standard was not meet because Dr. Levy's opinions conflict with facts of the natural history of the biology of these two diseases. Dec. TR 260; 384-386.

Daubert Factors

Testability. Case law requires testability according to the scientific method. In the instant

case, Dr. Levy's methodology and opinions are not testable because he did not follow the scientific method. As Dr. Gori stated, Dr. Levy's opinion does not meet the testability requirement according to the scientific method because it cannot be tested objectively, but only subjectively. Dec. TR 269.

Dr. Gori explains the scientific method as 1) an experiment should warrant to have measured what it says to have measured; 2) that the measurement should be accurate (you should have an error rate about what your measuring); and 3) are there any influences on the experiment that may corrupt a particular result that you are looking at. Dec. TR 267.

The main problem with Dr. Levy's methodology and opinions is that because there were no measurements of exposure/dosage in Dr. Levy's studies and because there was no measurements provided for the respective Plaintiffs, there is no way that his methodology or opinions or conclusions can be tested. Dr. Casella stated that Dr. Levy's methodology and opinions cannot be tested because if someone else repeated the study and extracted data in the same subjective manner, there is a good chance they will come up with different conclusions. Dec. TR 335. Dr. Borgert is very critical of Dr. Levy's methodology and found his methodology completely untestable; and there is no error rate that could be made from it. Dec. TR 367, 374. Dr. Borgert further found Dr. Levy's method untestable because there is no known error rate because of the various mixtures of chemicals in Dr. Levy's studies. Dr. Borgert also stated that he found Dr. Levy's methodology untestable because of Dr. Levy's lumping together different cancers that have different biology and his failing to take into account that there is a different biology which creates the possibility for different chemical mechanisms. Along those lines, Dr. Borgert also said that Dr. Levy's methodology is inherently untestable because you do not know what rules that he uses to select some data and what rules he uses to excludes the rest. You have to consider all of the biological data that is known, which Dr. Levy failed to do. Dec. TR 390, 400.

Error Rate. There is absolutely no way to figure an error rate on Dr. Levy's methodology and/or conclusions. Even Dr. Levy admitted that he did not have an error rate on the exposure data on any of the studies that he relied upon. He also admitted that he did not know the overall error rate on his opinions in this case. Dec. TR 118, 121.

Defendants' experts all said that no error rate could be determined from Dr. Levy's methodology and/or conclusions because of (1) unknown levels of exposures/dosage; (2) Dr. Levy's subjectivity; (3) unknown mixtures of chemicals in the studies that Dr. Levy relied upon; and (4) unknown measurements on the toxicological similarity. Dec. TR 263, 270, 321, 334-335, 366-367, 374-378, 380, 401.

Peer Review. Dr. Levy admitted that he has not published any opinions that benzene causes bladder cancer and Hodgkin's disease and that his opinions have not been subject to peer review. Nov. TR 76. In addition, Dr. Levy admitted that no studies to his knowledge have ever stated that the chemicals involved in our case have caused bladder cancer or Hodgkin's disease. Dec. TR 77-78. Dr. Gori also stated to his knowledge that Dr. Levy's opinions have not been peer reviewed. Dec. TR 272.

Scientific Acceptance. There is no question that Dr. Gori's opinions are not accepted in the scientific community. In fact, in an effort to find at least one epidemiologist that would support his opinions, Plaintiffs attempted to show that Dr. Goldstein in a 1986 article took the position that benzene was a likely cause of Hodgkin's disease. However, Defendants introduced a recent 2002 article written by the same Dr. Goldstein in which he changed his opinions substantially from that of 1986 stating that Hodgkin's disease findings are not at the level of scientific proof due in large part to the inherit weaknesses of epidemiology methodology. Dec. TR 305-307. See Defs' Exh. 17.

All of Defendants' experts were adamant that no one in the scientific community accepted

Dr. Levy's opinions; and that he is the only one that they were aware of that has actually opined benzene causes bladder cancer and Hodgkin's disease.

Additional Considerations

Another important and very significant fact to be considered is that Dr. Levy's opinions in this case did not grow naturally and directly out of research that he conducted independent to litigation; but were developed solely for purposes of testifying. Nov. TR 71. *Magistrini*, Supra at 594; *Daubert v. Merrill Dow Pharmaceuticals, Inc.*, 43 F. 3d, 1311, 1317 (9th Cir. 1995).

Conclusion

The Supreme Court in *Daubert* assigned the responsibility of "gatekeeper" to the District Court Judge to prevent expert testimony abuse by requiring the expert to base his opinions on the scientific method and not on his own subjectivity. In the instant case, we have the Plaintiffs' expert, Dr. Barry S. Levy disregarding the scientific method and scientific principles in an effort to arrive at a bias conclusion. Dr. Borgert testified that if one of his graduate students attempted Levy's methodology in the way that Levy performed it, it would not be acceptable, and he would explain to him/her what scientific misconduct is all about and how a scientist needs to be more comprehensive and more objective in the methods that they use. Dec. TR 402. In addition, Dr. Gori, a dedicated and renowned scientist, a protégée of Dr. Jonas Salk, a former Director of the Division of Cancer Causing Prevention at the National Cancer Institute stated that Dr. Levy's conclusions do not meet scientific requirements and do not meet the ethics as required by the National Academy of Sciences. Dec. TR 275.

Both Dr. Gori and Dr. Borgert agree that epidemiology is an acceptable science and can, under the right conditions, render causative opinions; however, the studies used by Dr. Levy, combined with his methodology, falls far short of what is scientifically acceptable.

Finally, there is no question that Dr. Levy's testimony on both bladder cancer and Hodgkin's disease fails to meet any of the ***Daubert*** requirements, and as such, is certainly inadmissible. His testimony/conclusions are not reliable.

Because of the brevity of the brief, I am attaching my summary of the trial testimony of Drs. Gori, Casella, and Borgert for a more complete assessment of Defendants' position.

RESPECTFULLY SUBMITTED, this 7th day of February, 2005.

s/Frank J. Dantone
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CERTIFICATE OF SERVICE

I, Frank J. Dantone, one of the attorneys of record for Defendants herein, do hereby certify that I have this date mailed postage prepaid, a true and correct copy of the above and foregoing to:

All counsels of Record

THIS, the 7th day of February, 2005.

s/Frank J. Dantone
Frank J. Dantone